

Dade Behring Marburg GmbH

2002/B001 - Ma 1248

Dr. Buck / Mi

Claims:

5

1. An antibody which binds selectively to carbohydrate deficient transferrin (CDT) in aqueous solution without the latter needing to be bound to a solid phase.

10

2. The antibody as claimed in claim 1, which does not bind or which binds insubstantially to the peptides P1 or P2 prepared according to EP-0 605 627.

15

3. The antibody as claimed in claim 2, whose binding behavior has been established in relation either to solid phase-bound peptides P1 or P2, or peptides P1 or P2 present in aqueous solution.

20

4. An antibody which binds selectively to CDT, wherein the binding takes place in the region of the following segments (1) to (4) of the CDT sequence:

(1) VVARSMGGKEDLIWELL and

(2) TTEDSIAKIMNGEADAMSLDGGF and

25

(3) SKLSMGSGNLSEPN and

(4) YEKYLGEELYVKAV.

30

5. The antibody as claimed in claim 4, wherein the binding takes place only in the region of three of the segments (1) to (4) of the sequence.

35

6. The antibody as claimed in claim 4, wherein the binding takes place only in the region of two of the segments (1) to (4) of the sequence.

7. The antibody as claimed in any of claims 1 to 6, which is a monoclonal antibody.

8. A monoclonal antibody which is produced by the cell culture having the deposition number DSM ACC2540.

9. A monoclonal antibody which is produced by the 5 cell culture having the deposition number DSM ACC2541.

10. An antigen-binding fragment which can be prepared from an antibody as claimed in any of the preceding claims 1 to 9.

10

11. A process for preparing the antibody as claimed in claim 1 by immunizing a suitable experimental animal with unglycosylated transferrin, fusing the spleen cells of this experimental animal to myeloma cells, 15 resulting in antibody-producing hybrid cells, cloning the hybrid cells and selecting a hybrid cell clone which produces an antibody which selectively binds to CDT in aqueous solution without the latter needing to be bound to a solid phase, and obtaining antibodies by 20 a process known to the skilled worker from the hybrid cell clone selected in this way.

12. A process for preparing the antibody as claimed in claim 4 by immunizing a suitable experimental animal 25 with unglycosylated transferrin, fusing the spleen cells of this experimental animal to myeloma cells, resulting in antibody-producing hybrid cells, cloning the hybrid cells and selecting a hybrid cell clone which produces an antibody whose binding according to 30 the results of an epitope mapping takes place in the region of the following segments (1) to (4) of the CDT sequence:

- (1) VVARSMGGKEDLIWELL and
- (2) TTEDSIAKIMNGEADAMSLDGGF and
- 35 (3) SKLSMGSGLNLSEPN and
- (4) YEKYLGEYVKAV;

and obtaining antibodies by a process known to the skilled worker from the hybrid cell clone selected in this way.

13. An immunoassay for detecting CDT in a sample,
which comprises bringing an antibody as claimed in any
of claims 1 to 9 or the antigen-binding fragment as
5 claimed in claim 10 into contact with the sample, and
determining qualitatively or quantitatively the
formation of an immune complex involving CDT.

14. A test kit for carrying out an immunoassay as
10 claimed in claim 13 comprising an antibody as claimed
in any of claims 1 to 9 or the antigen-binding fragment
as claimed in claim 10.